

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

**IN RE SUBOXONE (BUPRENORPHINE  
HYDROCHLORIDE AND NALOXONE)  
ANTITRUST LITIGATION**

**MDL No. 2445**

THIS DOCUMENT RELATES TO:  
*All Actions*

**Master File No. 2:13-MD-2445-MSG**

**DEFENDANT INDIVIOR INC.'S MEMORANDUM IN SUPPORT OF  
MOTION TO EXCLUDE FROM TRIAL REFERENCE TO INFORMATION FROM  
CRIMINAL AND FALSE CLAIMS ACT PROCEEDINGS**

## TABLE OF CONTENTS

INTRODUCTION .....	1
BACKGROUND .....	2
I.    PLAINTIFFS’ ANTITRUST CASE .....	2
II.   THE GOVERNMENT’S CRIMINAL CASES .....	2
III.  THE CIVIL FALSE CLAIMS ACT CASES .....	5
ARGUMENT .....	6
I.    EVIDENCE PERTAINING TO THE CRIMINAL PROCEEDINGS IS EITHER NOT RELEVANT OR MINIMALLY RELEVANT TO THIS ANTITRUST CASE .....	6
II.   ANY POTENTIAL PROBATIVE VALUE OF EVIDENCE FROM THE CRIMINAL PROCEEDINGS IS SUBSTANTIALLY OUTWEIGHED BY THE RISK OF UNFAIR PREJUDICE.....	8
III.  IN ADDITION TO BEING IRRELEVANT AND UNFAIRLY PREJUDICIAL, EVIDENCE THAT CERTAIN REPRESENTATIONS TO MASSHEALTH WERE THE SUBJECT OF CRIMINAL OR CIVIL FALSE CLAIMS ACT <i>QUI TAM</i> PROCEEDINGS IS INADMISSIBLE CHARACTER PROPENSITY EVIDENCE .....	11
IV.   EVIDENCE PERTAINING TO THE CIVIL FALSE CLAIMS ACT <i>QUI           TAM</i> AND CRIMINAL PROCEEDINGS SHOULD BE EXCLUDED FOR THE INDEPENDENT REASON THAT IT IS HEARSAY .....	13
A.   The Unproven Complaints And Indictments Are Inadmissible Hearsay .....	13
B.   The Information Charging Documents And Plea Agreements Of Non-Parties Are Also Inadmissible Hearsay .....	14
C.   The Public Statements Regarding The Criminal And Civil False Claims Act <i>Qui Tam</i> Proceedings Are Inadmissible Hearsay .....	15
V.    THE CIVIL SETTLEMENT AGREEMENT IS NOT ADMISSIBLE BECAUSE IT IS AN ACCEPTED OFFER OF COMPROMISE .....	16

VI.	THE PLEA AGREEMENTS ENTERED INTO BY NON-PARTIES THAXTER, BAXTER, AND SOLUTIONS ARE NOT ADMISSIBLE FOR IMPEACHMENT PURPOSES.....	17
	CONCLUSION.....	19

**TABLE OF AUTHORITIES**

	<b>Page(s)</b>
<b>Cases</b>	
<i>Alex v. Mgmt. &amp; Training Corp.</i> , 995 F. Supp. 2d 636 (S.D. Tex. 2012) .....	16
<i>Ansell v. Green Acres Contracting Co.</i> , 347 F.3d 515 (3d Cir. 2003).....	11
<i>Becker v. ARCO Chem. Co.</i> , 207 F.3d 176 (3d Cir. 2000).....	12
<i>Big Apple BMW Inc. v. BMW of N. Am., Inc.</i> , 974 F.2d 1358 (3d Cir. 1992).....	14
<i>Buckhead Theatre Co. v. Atlanta Enters., Inc.</i> , 327 F.2d 365 (5th Cir. 1964) .....	10
<i>Campbell v. City of New Kensington</i> , No. 05-0467, 2009 WL 3166276 (W.D. Pa. Sept. 29, 2009).....	16
<i>Coleman v. Wilson</i> , 912 F Supp. 1282 (E.D. Cal. 1995).....	15
<i>Dart Drug Corp. v. Parke, Davis &amp; Co.</i> , 344 F.2d 173 (D.C. Cir. 1965) .....	10
<i>Drake v. Allergan, Inc.</i> , No. 2:13-CV-234, 2014 WL 12717872 (D. Vt. Oct. 23, 2014).....	18
<i>Egan v. Del. River Port Auth.</i> , 851 F.3d 263 (3d Cir. 2002).....	8
<i>Foster v. Berwind Corp.</i> , No. 90-cv-0857, 1991 WL 83090 (E.D. Pa. May 14, 1991).....	13
<i>Gavurnik v. Vantage Labs, LLC</i> , 589 F. Supp. 3d 454 (E.D. Pa. 2022) .....	16
<i>Int'l Shoe Mach. Corp. v. United Shoe Mach. Corp.</i> , 315 F.2d 449 (1st Cir. 1963).....	10
<i>King Drug Co. of Florence, Inc. v. Cephalon, Inc.</i> , No. 2:06-cv-1797, 2016 WL 5928685 (E.D. Pa. Jan. 8, 2016).....	17

<i>Levinson v. Westport Nat. Bank,</i> No. 3:09cv269(VLB), 2013 WL 2181042 (C.D. Cal. May 20, 2013).....	13
<i>May v. Cooperman,</i> 780 F.2d 240 (3d. Cir. 1985) (Becker, J., dissenting).....	15
<i>McGhee v. Joutras,</i> No. 94 C 7052, 1996 U.S. Dist. LEXIS 18019 (N.D. Ill. Dec. 5, 1996) .....	13
<i>Michelson v. United States,</i> 335 U.S. 469 (1948).....	12
<i>Nelson v. Boro Properties, LLC,</i> No. 06-CV-2855, 2007 WL 9812994 (E.D. Pa. Sept. 27, 2007) .....	7
<i>Optional Cap., Inc. v. Kyung Joon Kim,</i> No. CV 04-3866, 2007 WL 9653243 (C.D. Cal. Dec. 18, 2007) .....	9
<i>Paramount Film Distrib. Corp. v. Vill. Theatre,</i> 228 F.2d 721 (10th Cir. 1955) .....	10
<i>Pathfinder Mgmt., Inc. v. Mayne Pharma PTY,</i> No. 06-CV-2204 (WJM), 2008 WL 3192563 (D. N.J. Aug. 5, 2008).....	14
<i>Portugues-Santana v. Rekomdiv Int’l,</i> 657 F.3d 56 (1st Cir. 2011).....	16
<i>S.E.C. v. Geon Indus., Inc.,</i> 531 F.2d 39 (2d Cir. 1976).....	15
<i>Southco, Inc. v. Fivetech Tech. Inc.,</i> 982 F. Supp. 2d 507 (E.D. Pa. 2013) .....	15
<i>T.I. Constr. Co. v. Kiewit E. Co.,</i> No. 91-2638, 1992 WL 382306 (E.D. Pa. Dec. 10, 1992).....	13
<i>Tajonera v. Black Elk Energy Offshore Operations, L.L.C.,</i> No. 13-0366, 2016 WL 9412702 (E.D. La. May 6, 2016).....	9
<i>U.S. Football League v. Nat’l Football League,</i> 842 F.2d 1335 (2d Cir. 1988).....	10
<i>U.S. ex rel. Underwood v. Genentech, Inc.,</i> No. 03-cv-3983, 2010 WL 8917474 (E.D. Pa. Oct. 7, 2010) .....	17
<i>United States v. Brackeen,</i> 969 F.2d 827 (9th Cir. 1992) .....	18

<i>United States v. Caldwell</i> , 760 F.3d 267 (3d Cir. 2014).....	12
<i>United States v. Cook</i> , 538 F.2d 1000 (3d Cir. 1976).....	8
<i>United States v. Cox</i> , 536 F.2d 65 (5th Cir. 1976) .....	13
<i>United States v. Davis</i> , 726 F.3d 434 (3d Cir. 2013).....	12
<i>United States v. Estrada</i> , 430 F.3d 606 (2d Cir. 2005).....	18
<i>United States v. Frierson</i> , No. 10-751, 2012 WL 652512 (E.D. Pa. Feb. 29, 2012) .....	12
<i>United States v. Hitt</i> , 981 F.2d 422 (9th Cir. 1992) .....	9
<i>United States v. Morley</i> , 199 F.3d 129 (3d Cir. 1999).....	12
<i>United States v. Rutland</i> , 372 F.3d 543 (3d Cir. 2004).....	8
<i>Walden v. Georgia-Pac. Corp.</i> , 126 F.3d 506 (3d Cir. 1997) (Becker).....	18, 19
<i>Williams v. Drake</i> , 146 F.3d 44 (1st Cir. 1998).....	9
<i>Y &amp; Y Popcorn Supply Co. v. ABC Vending Corp.</i> , 263 F. Supp. 709 (E.D. Pa. 1967) .....	11
<b>Statutes</b>	
21 U.S.C.A. § 331(a) .....	4, 18
21 U.S.C.A. § 333(a)(1).....	4, 17
15 U.S.C. § 16(a) .....	10
<b>Other Authorities</b>	
Fed. R. Evid. 401 .....	6, 10
Fed. R. Evid. 402 .....	6

Fed. R. Evid. 403 .....	8, 10, 12
Fed. R. Evid. 404 .....	11, 12
Fed. R. Evid. 408 .....	16, 17
Fed. R. Evid. 609 .....	17, 18
Fed. R. Evid. 801 .....	14, 15
Fed. R. Evid. 805 .....	15

## **INTRODUCTION**

Defendant Indivior Inc. (“Indivior”), moves the Court to exclude from trial reference to information from the civil False Claims Act actions against it and Indivior PLC, and the criminal actions against Indivior PLC, Indivior, its former employees, and its subsidiary Indivior Solutions (“Solutions”). Plaintiffs intend to offer at trial hundreds of pages from the criminal dockets in the Western District of Virginia, including an indictment and superseding indictment, informations, plea agreements, a resolution agreement, a civil settlement agreement, sentencing memoranda, character witness letters, and various exhibits in support of those filings. Although the *accusations* in these documents broadly relate to the marketing and sale of Suboxone Film, the factual admissions from the plea agreements entered into by Solutions and Indivior’s former employees are extremely limited, focusing only on two communications about a single statistical comparison of poison control data on buprenorphine products for a single state healthcare program made by a single rogue employee acting without the knowledge or permission of the employee’s superiors.

There is no factual evidence that these communications, which conveyed inaccurate data, were relied upon by the Massachusetts State Medicaid program (“MassHealth”). To the contrary, MassHealth cited to different—and accurate—published national data when announcing that it would reimburse its members for the purchase of Suboxone Film. When Indivior later corrected the inaccuracy contained in the two communications, MassHealth continued to cover film. As a result, information pertaining to the criminal cases and civil False Claims Act cases are either completely irrelevant, or minimally relevant to this antitrust case. But there is a substantial risk of unfair prejudice to Indivior if this information is introduced at trial, which seems to be Plaintiffs’ aim in seeking its admission. Given the lack of relevance of this information, the substantial risk of unfair prejudice, and the fact that it is contained in documents inadmissible for hearsay or other reasons, Indivior moves the Court to exclude outright all evidence pertaining to or referencing the

civil False Claims Act actions and the criminal proceedings of Shaun Thaxter, Timothy Baxter, Indivior PLC, Indivior, and Solutions. Alternatively Indivior moves the Court to admit into evidence only certain of the underlying facts by stipulation, so that Indivior is not unfairly prejudiced.

## **BACKGROUND**

### **I. PLAINTIFFS' ANTITRUST CASE**

Plaintiffs are a group of drug wholesalers and distributors who purchased Suboxone Film from Indivior's predecessor Reckitt Benckiser Pharmaceuticals, Inc. ("Reckitt"), and resold it to pharmacies. Plaintiffs claim that they would have made more money had they been able to buy and sell different products—either Suboxone Tablets or generic tablets—rather than Suboxone Film. According to Plaintiffs, this is Reckitt's fault—they allege that Reckitt allegedly engaged in anticompetitive conduct to coerce doctors and patients to demand Suboxone Film instead of tablets and caused Plaintiffs to sell more film and less tablets than they would have liked.

Plaintiffs base their claims on five categories of conduct, asserting broadly that it was anticompetitive for Reckitt to (1) develop Suboxone Film and discontinue Suboxone Tablets, (2) increase the price of Suboxone Tablets before they were discontinued, (3) claim that Suboxone Film is safer than Suboxone Tablets, (4) fail to come to an agreement with generic manufacturers in a shared Risk Evaluation and Mitigation Strategy ("REMS"), and (5) file a Citizen's Petition with the FDA requesting that it consider whether all buprenorphine products should be placed in child-resistant unit-dose packaging.

### **II. THE GOVERNMENT'S CRIMINAL CASES**

Around May and June of 2011, a purported physician acting at the behest of a predecessor to Indivior Solutions contacted a number of newspapers and MassHealth claiming that Suboxone Film was safer than alternatives. Neither the newspapers nor MassHealth published these claims.

Then, in October 2012, a medical affairs manager at the predecessor to Solutions, attempted to convince MassHealth that it should provide its members access to Suboxone Film by inaccurately adding together data on pediatric exposure rates that she received from the Researched Abuse, Diversion and Addiction-Related Surveillance (“RADARS”) system. Solutions Information ¶ 24, Ex. A. The employee’s actions made it appear that, at the time, Suboxone Film had the lowest rate of observed pediatric exposure in Massachusetts in comparison to Suboxone Tablets and Subutex (monotherapy) Tablets. *Id.* Although the employee had provided MassHealth accurate *national data* showing that during the five quarters Suboxone Film was marketed, it had the lowest rate of observed pediatric exposure of the three products, the employee’s inaccurate calculations disguised the fact that *Massachusetts* data showed that Subutex (monotherapy) Tablets actually had a lower rate of pediatric exposure than Suboxone Film. *Id.*

Two months later in December 2012, MassHealth announced that it would adjust its approval criteria to provide access to the unit-dosed Suboxone Film in households with children under the age of six. Ex. B. The announcement explained that a prior authorization request must be submitted for each prescription to obtain Suboxone Film. *Id.*

In support of this policy change, MassHealth cited *national data* from the abstract of a published study run by RADARS. RADARS Abstract, Ex. C. Consistent with the national data Solutions originally provided to MassHealth, the data highlighted in MassHealth’s announcement to beneficiaries showed that during the five quarters that Suboxone Film was marketed, the rates of observed pediatric exposure were 0.68 cases/1,000 unique recipients for the Tablets versus 0.08 cases/1,000 unique recipients for Film. *Id.* Neither the RADARS study nor the MassHealth announcement reference or contain any of the inaccurate calculations presented by the rogue medical affairs manager or any of the claims made by the purported physician. *Id.*

Indivior did not realize that the state data provided to Massachusetts was inaccurate until 2015 when it uncovered the improper calculations in emails the rogue employee sent to MassHealth as Indivior was complying with a government investigation. Indivior promptly notified MassHealth about the employee's misrepresentation. Solutions Information ¶ 27, Ex. A. MassHealth continued to reimburse for Suboxone Film.

Although the employee made misrepresentations to MassHealth, those misrepresentations appear to not have had any effect on either MassHealth or the market for Suboxone Film. But because of the significant responsibility the Food Drug and Cosmetic Act ("FDCA") places on corporate executives, the government pressed a Responsible Corporate Officer charge against Indivior's CEO Shaun Thaxter in relation to the rogue employee's actions. Even with no evidence of knowledge, intent, or criminal act, Thaxter pled guilty to the FDCA strict-liability misdemeanor charge<sup>1</sup> and was sentenced to six months in Federal prison. Ex. O. In response to a separate Responsible Corporate Officer charge against Indivior's then-Medical Director at the time of the rogue employee's actions, Tim Baxter pled guilty to the same strict liability misdemeanor in relation to the same employee's actions and was sentenced to six months of home detention. Because the rogue employee worked for Solutions, Solutions pled guilty to one count of making false statements relating to health care matters, committed to payments of \$290,000,000 and was excluded from participating in Federal health care programs. Solutions Plea Agreement at 1, 3, 9, Ex. D.

---

<sup>1</sup> The strict-liability misdemeanor was for causing the introduction or delivery for introduction into interstate commerce of a drug that is misbranded in violation of 21 U.S.C. §§ 331(a) and 333(a)(1), not an antitrust offense. The violation is for having responsibility and authority at Solutions when misrepresentations were made to MassHealth.

### III. THE CIVIL FALSE CLAIMS ACT CASES

Around the same time as the criminal investigation, six relators filed *qui tam* actions against various Indivior entities or predecessors to Indivior entities.<sup>2</sup> Settlement Agreement at 1-2, Ex. E. For the Virginia cases, the government partially intervened in August 2018 and for the New Jersey cases, the government intervened in July 2020.

In doing so, the government alleged that Indivior and Indivior PLC (1) promoted the sale and use of Suboxone to physicians who were writing prescriptions that were not for medically accepted indication, (2) promoted the sale and use of Suboxone Film with misleading claims about diversion, abuse and accidental pediatric exposure, and (3) submitted a petition to the FDA fraudulently claiming that Suboxone Tablet had been discontinued “due to safety concerns.” *Id.* at 3.

On July 24, 2020 Indivior settled these cases with an agreement to pay \$300,000,000. *Id.* at 4. At the time these cases were filed, Indivior denied their accusations, and in settling them, Indivior reaffirmed that the Agreement was not an admission of liability. *Id.* at 3. Indivior stipulated that Solutions made the misrepresentations that were the basis of the Solutions plea agreement.

---

<sup>2</sup> Listed in the Settlement as:

*United States ex. rel. Kruszewski v. Reckitt Benckiser Pharms., Inc.* (D.N.J.)  
*United States ex. rel. Finkelstein v. Reckitt Benckiser Pharms., Inc.* (W.D. Va.)  
*United States ex. rel. Williams v. Reckitt Benckiser, Inc.* (W.D. Va.)  
*United States ex. rel. Scott v. Reckitt Benckiser Pharms.* (D.N.J.)  
*United States ex. rel. Lemons v. Reckitt Benckiser Pharms.* (W.D. Va.)  
*United States ex. rel. Greene v. Indivior PLC* (D.N.J.)

## ARGUMENT

### **I. EVIDENCE PERTAINING TO THE CRIMINAL PROCEEDINGS IS EITHER NOT RELEVANT OR MINIMALLY RELEVANT TO THIS ANTITRUST CASE**

No evidence is admissible unless it is relevant. Fed. R. Evid. 402. Evidence is relevant only if it has a “tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.” Fed. R. Evid. 401. Although the government accused Indivior of broad criminal misconduct and then joined *qui tam* relators to accuse Indivior of similarly broad misconduct in their civil False Claims Act allegations, those accusations are just that—accusations; unproven out-of-court statements of non-parties.

Indivior never pleaded guilty to any crime. The various complaints, informations, and indictments were dismissed in connection with the Solutions plea agreement. Indivior’s civil settlement and criminal resolution agreement did not admit any of the allegations in the superseding indictment or the civil *qui tam* actions in which the government partially intervened. Those accusations remain unproven to this day. They are not probative of anything.

As for Solutions—which is not a party to this case—there are two components to the information from the criminal proceedings in the Western District of Virginia. First, there are the underlying facts describing what Solutions’ rogue employee sent to MassHealth. Second there is the context in which those facts were gathered and presented—a criminal investigation and its resolution by plea agreement.

At most, the underlying facts presented in the criminal proceedings could be conditionally relevant if Plaintiffs could show that someone was prescribed Suboxone Film instead of Suboxone Tablet or generic tablets based on the false communications with MassHealth. This is an antitrust case requiring proof of antitrust injury and coercion. And no such evidence exists. Instead, (1)

misrepresentations were made to MassHealth by email, (2) MassHealth cited different information in its coverage announcement explaining why it would provide access for Suboxone Film, and (3) no record evidence shows that rogue employee's email or its accompanying misrepresentation were published or relayed to anyone other than the single MassHealth official. The underlying facts are also not probative of any broader Indivior scheme because, as even the government acknowledged, Indivior's CEO was not aware of the rogue employee's inaccurate email to MassHealth until he learned about it in December 2015 and promptly authorized a notice and correction letter. Thaxter Information ¶ 31, Ex. P.

But even if Plaintiffs could show that the rogue employee's actions on behalf of Solutions had some slight relevance, the context in which these facts were made known (in a criminal investigation and plea agreement) has no tendency to make Plaintiffs' antitrust claims more or less probable. Thus, if the underlying facts are found to be admissible, they should be presented by narrow stipulation, as in the footnote below,<sup>3</sup> or not at all. *See, e.g., Nelson v. Boro Properties,*

- 
- <sup>3</sup> 1. On or about October 16, 2012, a medical affairs manager at a predecessor to Indivior Solutions ("Solutions"), sent an email to Massachusetts' Medicaid ("MassHealth") presenting data from the Researched Abuse, Diversion and Addiction-Related Surveillance ("RADARS") System to appear as though Reckitt's Suboxone film had the lowest rate of observed pediatric exposure in Massachusetts, when in reality Reckitt's Subutex tablets had a lower rate of observed pediatric exposure in Massachusetts.
  2. Also in October, Reckitt provided MassHealth with national data from RADARS showing that for the five quarters during which Suboxone Film had been marketed, observed pediatric exposures to Suboxone tablets (average 0.68 cases/1,000 URDD; 95% CI: 0.64 – 0.73) were more common than observed pediatric exposures to Suboxone Film (average 0.08 cases/1,000 URDD; 95% CI: 0.07 – 0.10; rate ratio 8.1; 95% CI: 6.5 – 10.0;  $p < 0.0001$ ).
  3. In December 2012, MassHealth announced that it would provide access to Suboxone Film to those members prescribed Suboxone who live in households with children less than six years of age, so long as a prior authorization request was submitted stipulating to this circumstance.

*LLC*, No. 06-CV-2855, 2007 WL 9812994, at \*2-3 (E.D. Pa. Sept. 27, 2007) (finding that certain information obtained during a criminal investigation might be relevant, but that it needed to be presented “without framing its procurement in the context of [a party’s] arrest”).

## **II. ANY POTENTIAL PROBATIVE VALUE OF EVIDENCE FROM THE CRIMINAL PROCEEDINGS IS SUBSTANTIALLY OUTWEIGHED BY THE RISK OF UNFAIR PREJUDICE**

Even relevant evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury. *See Egan v. Del. River Port Auth.*, 851 F.3d 263, 275 (3d Cir. 2002) (citing Fed. R. Evid. 403). In this context, “unfair prejudice ‘means an undue tendency to suggest decision on an improper basis, commonly, though not necessarily, an emotional one.’” *United States v. Rutland*, 372 F.3d 543, 546 (3d Cir. 2004) (quoting Fed. R. Evid. 403 Advisory Committee’s note). In weighing the probative value of evidence—especially the probative value of other criminal proceedings—against the risk of unfair prejudice, the court should take into account other, less prejudicial evidence that a party might have at its disposal. *See United States v. Cook*, 538 F.2d 1000, 1003-04 (3d Cir. 1976).

Here, any arguable probative value of evidence showing that certain conduct was subject to criminal proceedings is substantially outweighed by the risks that this evidence will unduly prejudice Indivior, confuse the issues, or mislead the jury. Plaintiffs allege that Reckitt has *never* had sufficient data to claim that Suboxone Film is safer than tablets. Plaintiffs’ Responses and Objections to Indivior’s Statements of Undisputed Material Facts #225. And Plaintiffs claim that they have many sources of evidence—evidence unrelated to the criminal plea agreements—demonstrating that Indivior misled doctors, patients, and payors. *See 2/23/2015 DPP Second*

---

4. MassHealth’s announcement cited to the accurate RADARS national data which did not reference or mention in any way the Massachusetts-specific data that the medical affairs manager had provided.

Amended Class Action Complaint (filed prior to Indivior’s realization of misrepresentations to MassHealth listing allegedly “deceptive tactics”). The only reasons to elicit testimony or present evidence about the misrepresentations to MassHealth and how that conduct *was subject to criminal proceedings* would be to inflame the jury against Indivior and potentially provoke the jury’s desire to punish Indivior for conduct that has been labeled criminal. Whatever marginal value such evidence might possess is substantially outweighed by the risks. *See Williams v. Drake*, 146 F.3d 44, 48 (1st Cir. 1998) (affirming exclusion of guilty plea with “relatively low probative value and [the] potential for breeding confusion, distraction, and undue prejudice”); *United States v. Hitt*, 981 F.2d 422, 424 (9th Cir. 1992) (“Where the evidence is of very slight (if any) probative value, it’s an abuse of discretion to admit it if there’s even a modest likelihood of an unfair prejudice or a small risk of misleading the jury.”). As a result, any evidence or references to the purported criminality of certain conduct should be excluded. *See, e.g., Tajonera v. Black Elk Energy Offshore Operations, L.L.C.*, No. 13-0366, 2016 WL 9412702, at \*3 (E.D. La. May 6, 2016) (excluding references to criminal proceedings in related civil action); *Optional Cap., Inc. v. Kyung Joon Kim*, No. CV 04-3866, 2007 WL 9653243, at \*3 (C.D. Cal. Dec. 18, 2007) (same).

The potential for unfair prejudice is particularly acute here because Thaxter, Baxter, and Solutions pled guilty to misbranding charges, not antitrust violations. Whatever relevance the rogue employee’s data misrepresentations might have to the antitrust case—and the underlying facts of the conduct are undisputed and can be presented by stipulation—the criminal charges and pleas based upon those misrepresentations simply are not relevant to this antitrust action. The criminal charges and pleas do not, as a matter of fact and law, tend to make the likelihood of an antitrust violation any greater or lesser. But they are extraordinarily and unfairly prejudicial because the jury could deliberately punish Indivior for the criminal violation despite the fact the

violation had nothing to do with the antitrust laws. Perhaps worse, the jury could become confused—inadvertently or deliberately misled by Plaintiffs—and punish Indivior, believing that the criminal violation actually did have something to do with the antitrust laws. Fed. R. Evid. 403 (noting danger of “confusing the issues” and “misleading the jury”).

While Congress created a narrow exception for plaintiffs to use prior *antitrust* judgments in a subsequent civil action, there is no statute that permits plaintiffs to rely upon prior non-antitrust judgments. *See* 15 U.S.C. § 16(a). Even where the prior judgment actually involved an antitrust violation—unlike here—courts exclude judgments from subsequent civil antitrust cases under Rules 401 and 403. *See, e.g., U.S. Football League v. Nat’l Football League*, 842 F.2d 1335, 1373 (2d Cir. 1988) (“The district court thus acted within its discretion in excluding evidence of prior antitrust judgments against the NFL on the grounds that their prejudicial value outweighed their probative value under Fed. R. Evid. 403.”); *Dart Drug Corp. v. Parke, Davis & Co.*, 344 F.2d 173, 185 (D.C. Cir. 1965) (“[W]e do not believe that [the plaintiff] should be able to use the prior judgment as a crutch in the attempt to supply the essential elements of his action. It would be subversive of the purpose of Section 5 to permit the introduction of a prior decree or judgment ‘merely for its aura of guilt, or ‘to imply new wrongdoing from past wrongdoing.’”) (citation omitted); *Buckhead Theatre Co. v. Atlanta Enters., Inc.*, 327 F.2d 365, 368–69 (5th Cir. 1964) (affirming exclusion of prior antitrust judgments where the conduct underlying those judgments did not have a direct, logical relationship to the conduct at issue in the subsequent case); *Int’l Shoe Mach. Corp. v. United Shoe Mach. Corp.*, 315 F.2d 449, 459 (1st Cir. 1963) (“Whether admitted purely as ‘background’ evidence or not, evidence of a judicial determination of prior illegal [anticompetitive] conduct on the part of the defendant cannot help but have a great emotive impact on a jury.”); *Paramount Film Distrib. Corp. v. Vill. Theatre*, 228 F.2d 721, 727 (10th Cir. 1955)

(“We can find no issue adjudicated in the Paramount decree which would be material to any issue in the instant case, or would constitute an estoppel as against any party to the instant case. We conclude that the trial court committed prejudicial error in admitting such decree.”); *Y & Y Popcorn Supply Co. v. ABC Vending Corp.*, 263 F. Supp. 709, 713 (E.D. Pa. 1967) (finding the FTC consent order inadmissible where it was questionable whether “the decree would have any probative value at all as to the merits of this case” and where the evidence would be “so potently prejudicial and its ‘emotion impact’ (especially in a jury case) so great”).

These decisions apply with even greater force here, where the prior judgment is for an irrelevant misbranding charge not an antitrust violation. Because the non-antitrust violations are not relevant, the scales easily tip in favor of excluding the evidence when weighing relevance and the extreme prejudice here. Admitting evidence showing that the government already has determined that an Indivior subsidiary should be punished (for reasons unrelated to the antitrust laws) for past statements about Suboxone products would make it very hard for the jury to fairly view the actual evidence when evaluating whether Indivior’s statements regarding Suboxone harmed competition and violated the antitrust (as opposed to misbranding) laws. The evidence therefore should be excluded.

**III. IN ADDITION TO BEING IRRELEVANT AND UNFAIRLY PREJUDICIAL, EVIDENCE THAT CERTAIN REPRESENTATIONS TO MASSHEALTH WERE THE SUBJECT OF CRIMINAL OR CIVIL FALSE CLAIMS ACT *QUI TAM* PROCEEDINGS IS INADMISSIBLE CHARACTER PROPENSITY EVIDENCE**

Under Federal Rule of Evidence 404(b)(1), “[e]vidence of any other crime, wrong, or act is not admissible to prove a person’s character in order to show that on a particular occasion the person acted in accordance with the character.” Regardless of whether the other act evidence relates to prior acts or subsequent acts, so long as it is being offered for a propensity purpose, it is inadmissible. *See Ansell v. Green Acres Contracting Co.*, 347 F.3d 515, 520 (3d Cir. 2003). Rule

404(b)(1) reflects concern that a jury will give too much weight to other acts and deny the defendant “a fair opportunity to defend against a particular charge.” *United States v. Davis*, 726 F.3d 434, 440 (3d Cir. 2013) (quoting *Michelson v. United States*, 335 U.S. 469, 476 (1948)).

In the Third Circuit, other acts evidence is only admissible if (1) it is relevant, (2) it has a non-propensity purpose, (3) its probative value outweighs its prejudicial effect under Rule 403, and (4) the jury is charged to only consider the evidence for the limited purpose for which it was admitted. *Becker v. ARCO Chem. Co.*, 207 F.3d 176, 189 (3d Cir. 2000). To show a proper purpose, the party offering the evidence must clearly “explain how it fits into a chain of inferences—a chain that connects the evidence to a proper purpose, no link of which is a forbidden propensity inference.” *United States v. Caldwell*, 760 F.3d 267, 277 (3d Cir. 2014) (citation omitted). “The prime inquiry is whether the evidence is probative of a material issue other than character.” *See United States v. Frierson*, No. 10-751, 2012 WL 652512, at \*4 (E.D. Pa. Feb. 29, 2012).

Even if the rogue employee’s misrepresentations to MassHealth were relevant to this antitrust case—which they are not—the fact that the misrepresentations involved criminal and *qui tam* proceedings is inadmissible character propensity evidence. Its sole purpose is a forbidden one—that because Solutions, a company that is not a party here, made a *criminal* misrepresentation previously, an affiliated Indivior entity, Indivior Inc., has a propensity for criminality and is therefore more likely to have committed an *antitrust* violation by making the wrongful misrepresentations claimed in the instant case. This inference “is the very evil that Rule 404(b) seeks to prevent” and it should therefore be excluded. *United States v. Morley*, 199 F.3d 129, 134 (3d Cir. 1999).

**IV. EVIDENCE PERTAINING TO THE CIVIL FALSE CLAIMS ACT *QUI TAM* AND CRIMINAL PROCEEDINGS SHOULD BE EXCLUDED FOR THE INDEPENDENT REASON THAT IT IS HEARSAY**

Plaintiffs intend to introduce three categories of hearsay evidence pertaining to the civil *qui tam* and criminal proceedings: (A) various accusations against Indivior in complaints and indictments, (B) various accusations by information against non-parties and plea agreements of non-parties, and (C) public statements about the civil and criminal investigations and resolutions. They all should be excluded.

**A. The Unproven Complaints And Indictments Are Inadmissible Hearsay**

The relator's "[c]omplaints, and the charges and allegations they contain, are hearsay under the Federal Rules of Evidence." *T.I. Constr. Co. v. Kiewit E. Co.*, No. 91-2638, 1992 WL 382306, at \*4 (E.D. Pa. Dec. 10, 1992); *see also Foster v. Berwind Corp.*, No. 90-cv-0857, 1991 WL 83090, at \*1 (E.D. Pa. May 14, 1991) ("The allegations, however, in the complaints in these other actions are just that: allegations. To begin examining and admitting evidence of accusations [would be] dispositive of nothing and would confuse the complex issues already present."). The same is true for the government's indictment and superseding indictment. *Levinson v. Westport Nat. Bank*, No. 3:09cv269(VLB), 2013 WL 2181042, at \*1–\*2 (C.D. Cal. May 20, 2013); *see also McGhee v. Joutras*, No. 94 C 7052, 1996 U.S. Dist. LEXIS 18019, at \*19–\*20, \*26 (N.D. Ill. Dec. 5, 1996) ("As imaginative as lawyers may be, it still takes considerable nerve even to make the argument [that an indictment may be admitted into evidence in a civil case]."). "It is hornbook law that indictments cannot be considered as evidence." *United States v. Cox*, 536 F.2d 65, 72 (5th Cir. 1976). Thus, the *qui tam* relators' complaints and the government's indictments, as well as the allegations they contain, should be excluded. *See* Pls. Proposed Exs. Indictment, Ex. F; Superseding Indictment, Ex. G; Relator Second Amended Complaint, Ex. H.

**B. The Information Charging Documents And Plea Agreements Of Non-Parties Are Also Inadmissible Hearsay**

The Court should also exclude the informations and related plea agreements that Solutions, Thaxter, and Baxter—all non-parties to this action—made in the Western District of Virginia criminal proceedings. The informations, plea agreements, and statements they contain, are out-of-court statements and cannot be offered for the truth of the matter therein. *See* Fed. R. Evid. 801(c). No exception to the hearsay rule applies.

The informations and the plea agreements do not fall within the opposing-party statement exception to the hearsay rule. Rule 801(d)(2)(D) provides a hearsay exception for a statement offered against an opposing party that “was made by the party’s agent or employee on a matter within the scope of that relationship and while it existed[.]” But Solutions, Thaxter, and Baxter were not Indivior’s agents or employees when they made their pleas, as required under this exception.

As to Solutions, “[t]he statement of a subsidiary may be attributed to its corporate parent, consistent with agency theory, where the parent dominates the activities of the subsidiary.” *Big Apple BMW Inc. v. BMW of N. Am., Inc.*, 974 F.2d 1358, 1373 (3d Cir. 1992). As this Court noted, “[s]imply being a wholly-owned subsidiary of a parent corporation alone does not make the subsidiary the agent of the parent, rather a parent corporation will be liable for the activities of the subsidiary only if the parent dominates those activities. Under this theory, only the conduct shown to be instigated by the parent may be attributed to the parent.” Mem. Op., ECF No. 401 (Oct. 25, 2017) at 25 (internal citations and quotations omitted).

Here, Plaintiffs cannot satisfy this stringent requirement. There is no evidence Solutions pled guilty at the behest of Defendant. “The mere fact that a corporation’s boards of directors or officers overlap cannot establish a parent’s domination or control of the subsidiary.” *Pathfinder*

*Mgmt., Inc. v. Mayne Pharma PTY*, No. 06-CV-2204 (WJM), 2008 WL 3192563, at \*5 (D. N.J. Aug. 5, 2008). And “[t]he mere fact that [Defendant]’s CEO bears responsibility for the management of the day-to-day operations of [Solutions], strategic planning of the group, and supervising subsidiary teams does not create any reasonable inference that [Indivior] either directed or perpetuated” its subsidiary’s statements. Mem. Op., ECF No. 401 (Oct. 25, 2017) at 25. Therefore, Solutions’ plea cannot be considered a statement made by Defendant or its agent.

The same is true for the pleas made by Thaxter and Baxter because both made their pleas after they left the company. Thaxter signed his plea agreement on June 29, 2020 after he resigned from Indivior on June 27, 2020. Baxter signed his plea on August 28, 2020, over four years after he left Indivior on May 20, 2016. *See* Baxter Information ¶ 3, Ex. I. Because their guilty pleas were not made during their employment with Indivior, their pleas cannot be considered an admission by Defendant’s employees under Rule 801(d)(1)(D). *Coleman v. Wilson*, 912 F Supp. 1282, 1296 (E.D. Cal. 1995); *see also S.E.C. v. Geon Indus., Inc.*, 531 F.2d 39, 43 n.3 (2d Cir. 1976) (holding an employee’s testimony, given after he had been suspended from employment, was inadmissible against the defendant-employer).

**C. The Public Statements Regarding The Criminal And Civil False Claims Act *Qui Tam* Proceedings Are Inadmissible Hearsay**

The newspaper articles and press releases related to the criminal and civil False Claims Act *qui tam* proceedings are inadmissible hearsay. *See Southco, Inc. v. Fivetech Tech. Inc.*, 982 F. Supp. 2d 507, 514 (E.D. Pa. 2013); *see also May v. Cooperman*, 780 F.2d 240, 262 n.10 (3d. Cir. 1985) (Becker, J., dissenting) (“Ordinarily, when offered to prove the truth of the matters stated therein, newspaper articles are held inadmissible as hearsay.”). Moreover, the newspaper articles and the press releases on Plaintiffs’ exhibit list implicate hearsay within hearsay. *See* Fed. R. Evid. 805; Pls. Proposed Exs. DOJ News, Ex. J; DOJ Press Release, Ex. K. For example, Plaintiffs

include on their exhibit list an April 10, 2019 Financial Times article which discusses Indivior's indictment and includes statements from investors and analysts. *See* Proposed Exs. News Article, Ex. L ("analysts at Jefferies said Indivior 'may struggle to finance even a 50 per cent share of the proposed fine.'"). Similarly, Plaintiffs include on their proposed exhibit list a July 24, 2020 DOJ press release discussing Defendant's resolution agreement, which incorporates statements from numerous non-DOJ officials, including the Virginia Attorney General, FDA Commissioner, Deputy Director of the FTC's Bureau of Competition, Chief Counsel to the Inspector General of HHS, and special agent for the U.S. Postal Service. *See* DOJ Press Release, Ex. K. This hearsay evidence should be excluded. *See Campbell v. City of New Kensington*, No. 05-0467, 2009 WL 3166276, at \*8 (W.D. Pa. Sept. 29, 2009) (excluding the newspaper articles because they "are hearsay, and in some instances, hearsay within hearsay"); *see also Alex v. Mgmt. & Training Corp.*, 995 F. Supp. 2d 636, 641 (S.D. Tex. 2012) (sustaining objections regarding double hearsay in DOJ press release).

**V. THE CIVIL SETTLEMENT AGREEMENT IS NOT ADMISSIBLE BECAUSE IT IS AN ACCEPTED OFFER OF COMPROMISE**

Pursuant to Rule 408, evidence of a settlement is inadmissible to prove the validity of a prior claim. *Gavurnik v. Vantage Labs, LLC*, 589 F. Supp. 3d 454, 468 (E.D. Pa. 2022) (citing Fed. R. Evid. 408 (a)). "Courts have held that this rule applies equally to settlement agreements between a defendant and a third party." *Id.* (citation and quotation omitted). This is so "because the admission of such evidence would discourage settlements in either case." *Portugues-Santana v. Rekomdiv Int'l*, 657 F.3d 56, 63 (1st Cir. 2011) (citation and quotation omitted).

Plaintiffs have indicated that they intend to use as a trial exhibit the Civil Settlement Agreement between Indivior and Indivior PLC on one side and the United States and individual relators on the other side. Plaintiffs have listed it as a standalone exhibit and as an attachment to

the Solutions Plea Agreement and Indivior Resolution Agreement. *See* Exs. E, M, N. Regardless of its form, the Civil Settlement Agreement is inadmissible.

This is not a situation in which the agreements are being proffered for a potential exception. The only reason for this document to be introduced is to make known to the jury that Indivior was investigated by the government and that it paid hundreds of millions of dollars to bring the matter to a close. In addition to being irrelevant, unfairly prejudicial, likely offered to show propensity, and hearsay, the Civil Settlement is inadmissible under Rule 408, so as not to dissuade compromise. If these types of settlement agreements were admissible in future cases, they would lose their effectiveness. Indivior resolved the *qui tam* action without admitting fault of any kind, and so the allegations in the *qui tam* complaints were never litigated. To preserve the compromise of the parties and prevent the jury from drawing erroneous conclusions, the Court should exclude reference to the civil investigation, *qui tam* complaints, government partial intervention, and civil settlement. *See King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, No. 2:06-cv-1797, 2016 WL 5928685, at \*2 (E.D. Pa. Jan. 8, 2016) (excluding reference to FTC investigation, lawsuit, and settlement); *U.S. ex rel. Underwood v. Genentech, Inc.*, No. 03-cv-3983, 2010 WL 8917474, at \*2 (E.D. Pa. Oct. 7, 2010) (protecting *qui tam* settlement materials under Rule 408).

**VI. THE PLEA AGREEMENTS ENTERED INTO BY NON-PARTIES THAXTER, BAXTER, AND SOLUTIONS ARE NOT ADMISSIBLE FOR IMPEACHMENT PURPOSES**

Plaintiffs cannot use the plea agreements of Thaxter and Baxter to impeach their testimony. Federal Rules of Evidence 609(a)(1) does not apply because the crime to which Thaxter and Baxter pled guilty is not punishable by more than a year. Fed. R. Evid. 609(a)(1); 21 U.S.C.A. § 333(a)(1) (West).

The Court cannot admit them under Rule 609(a)(2) either. The Third Circuit has “held that Rule 609(a)(2) must be construed narrowly to apply only to those crimes that bear on a witness’

propensity to testify truthfully.” *Walden v. Georgia-Pac. Corp.*, 126 F.3d 506, 523 (3d Cir. 1997) (Becker). Further, courts in other circuits have held that, to qualify as a Rule 609(a)(2) crime, the crime has to have an element of intent or disposition to deceive. *See United States v. Brackeen*, 969 F.2d 827, 829-30 (9th Cir. 1992) (“The legislative history of Rule 609 makes clear that Congress used the term “dishonesty” in the narrower sense, to mean only those crimes which involve deceit.”); *United States v. Estrada*, 430 F.3d 606 (2d Cir. 2005) (same).

The plea agreements for Thaxter and Baxter do not admit or even address deception. Although they pled guilty to a misdemeanor under 21 U.S.C.A. § 331(a), the statute does not require *mens rea* or an intent to deceive, and neither Thaxter nor Baxter had direct involvement in the wrongdoing. Indeed, neither the informations nor the Thaxter and Baxter plea agreements assert or admit knowledge of the misrepresentations, intent to deceive, or analogous conduct. Thaxter Plea ¶ 1, Ex. O; Thaxter Information ¶ 31, Ex. P; Baxter Plea ¶ 1, Ex. Q; Baxter Information ¶ 31, Ex. I. If the government had asserted that Thaxter or Baxter had the intent to defraud or deceive, the applicable offense would have been a felony. *See Drake v. Allergan, Inc.*, No. 2:13-CV-234, 2014 WL 12717872, at \*3 (D. Vt. Oct. 23, 2014) (finding plaintiff could not impeach with defendant’s plea agreement for misdemeanor misbranding). Because the plea agreements of Indivior’s former employees have no bearing on their “propensity to testify truthfully,” they are inadmissible for impeachment purposes. *See Walden*, 126 F.3d at 523.

Plaintiffs cannot use Solution’s criminal conviction to impeach Thaxter and Baxter, either. “It is only the testifying witness’ own convictions that will bear directly on the likelihood that he or she will testify truthfully.” *Id.* Accordingly, “it is axiomatic that it is only the testifying witness’ own prior convictions that should be admissible on cross-examination to impeach his credibility.” *Id.* For Plaintiffs to use Solutions’ guilty plea to impeach Indivior’s employees, Plaintiffs would

first have to show that Solutions’ criminal conduct was the “individual employee’s ‘own’ in some meaningful fashion.” *Id.* But because Solutions’ plea agreement only admits facts as to the conduct of the rogue employee and purported physician, and the misbranding charge was only extended to Thaxter and Baxter as officers in the broader corporate structure, Solutions’ plea does not bear on the likelihood that Thaxter or Baxter will testify truthfully. Therefore, Solutions’ guilty plea should not be admissible to impeach Thaxter or Baxter.

### **CONCLUSION**

Rather than prove Indivior violated the antitrust laws by excluding generic competition, Plaintiffs are trying to make this case about unproven criminal allegations, insinuations, and inferences. The probative value of the evidence pertaining to the civil False Claims Act *qui tam* and criminal proceedings is nonexistent, the risk of unfair prejudice is significant, and the sources for this evidence are inadmissible hearsay. Therefore, for these reasons and the reasons in the foregoing Memorandum, Defendant Indivior, Inc. requests that the Court exclude from trial all evidence pertaining to or referencing the civil *qui tam* against it and Indivior PLC, and the criminal actions against Indivior PLC, Indivior, its former employees, and its subsidiary Indivior Solutions (“Solutions”).

Dated: September 1, 2023

Respectfully Submitted,

/s/ Virginia A. Gibson  
Virginia A. Gibson (PA #32520)  
HOGAN LOVELLS US LLP  
1735 Market Street, 23rd Floor  
Philadelphia, PA 19103  
(267) 675-4635  
virginia.gibson@hoganlovells.com

Justin W. Bernick (*pro hac vice*)  
Ilana Kattan (*pro hac vice*)  
HOGAN LOVELLS US LLP  
555 Thirteenth Street, NW  
Washington, DC 20004  
(202) 637-5485  
justin.bernick@hoganlovells.com  
ilana.kattan@hoganlovells.com

N. Thomas Connally (*pro hac vice*)  
HOGAN LOVELLS US LLP  
8350 Broad Street, 17th Floor  
Tysons, VA 22102  
(703) 610-6126  
tom.connally@hoganlovells.com

Jillian C. Beck (*pro hac vice*)  
HOGAN LOVELLS US LLP  
609 Main Street, Suite 4200  
Houston, TX 77002  
(713) 632-1465  
jillian.beck@hoganlovells.com

Tiffany D. Lipscomb-Jackson (*pro hac vice*)  
JONES DAY  
325 John H. McConnell Boulevard, Suite 600  
Columbus, OH 43215  
(614) 281-3876  
tdlipscombjackson@jonesday.com

*Counsel for Defendant Indivior Inc.*